DEC 1 0 2002

K023732

PART VIII. 510(K) SUMMARY

In response to the requirements addressed by the Safe Medical Devices Act (SMDA) of 1990, a summary follows with the safety and effectiveness information upon which the substantial equivalence determination is based.

SUMMARY OF SAFETY AND EFFECTIVENESS FOR CIBASOFT® PROGRESSIVE TORIC Soft (hydrophilic) Contact Lenses

1. **Submitter Information**

CIBA Vision Corporation
11460 Johns Creek Parkway
Duluth, Georgia 30097
Contact Person:Terrina Wilder
Telephone No. 678-415-3809

2. **Device Name**

Classification Name:	Soft (hydrophilic) Contact Lens
Proprietary Name:	CIBASOFT® PROGRESSIVE TORIC Soft (hydrophilic) Contact Lens

3. **Predicate Device**

TORISOFT® Soft (hydrophilic) Contact Lens (PMA #810005)

4. **Description of the Device**

CIBASOFT® PROGRESSIVE TORIC soft contact lenses are hemispherical flexible shells made of tefilcon, a hydrophilic polymer of hydroxyethylmethacrylate (HEMA), with a water content of 37.5% by weight in normal saline solution. The lens is available in 8.6mm and 8.9mm base curves, 14.5mm diameter with center thickness of 0.012mm at -3.00 diopters or 0.014mm at +3.00 diopters, and powers ranges from -25.00 to +25.00diopters. CIBASOFT® PROGRESSIVE TORIC has a toric optic zone on its front surface with a centermost aspheric zone on its back surface. This aspheric zone has an add power range from 0.25 to 0.75 diopters for vision correction at near. For optimum stabilization of the lens on the cornea, there are two thin zones on the front surface at the 12 o'clock and 6 o'clock positions.

5. **Indications for Use**

CIBASOFT® PROGRESSIVE TORIC (tefilcon) soft (hydrophilic) contact lenses are indicated for daily wear for the correction of refractive ametropia (myopia, hyperopia, astigmatism and presbyopia) in aphakic or not aphakic persons with non-diseased eyes. The lenses may be worn by persons who have 0.75 to 2.75 diopters of refractive and/or corneal astigmatism that does not interfere with visual acuity.

6. **Description of Safety and Substantial Equivalence**

CIBASOFT® PROGRESSIVE TORIC lenses represent a modification to CIBA Vision's TORISOFT® lenses. Both lenses are made of the same tefilcon material and manufactured by a back curve molded/front curve lathed process (commonly known as the B0011 process). The addition of the multifocal or presbyopic feature to the centermost part of optical zone of the base curve, does not raise new safety or efficacy issues, thus, CIBASOFT® PROGRESSIVE TORIC is substantially equivalent to the TORISOFT® lens.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

DEC 1 0 2002

CIBA Vision Corporation
C/O Terrina Wilder
11460 Johns Creek Parkway
Duluth, GA 30097-1556

Re: K023732
Trade/Device Name: CIBASOFT ® PROGRESSIVE TORIC (tefilcon) Hydropilic Contact Lens for Daily Wear
Regulation Number: 21 CFR 886.5925
Regulation Name: Soft (hydrophilic) contact lens
Regulatory Class: Class II
Product Code: LPL
Dated: November 4, 2002
Received: November 6, 2002

Dear Ms. Wilder:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 21 CFR Part 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4613. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,

A. Ralph Rosenthal

A. Ralph Rosenthal, M.D.
Director
Division of Ophthalmic and Ear,
Nose and Throat Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

PART III. INDICATIONS FOR USE STATEMENT

510(k) Number: *K023732*

Device Name: **CIBASOFT® PROGRESSIVE TORIC (tefilcon) Soft (hydrophilic) Contact Lens**

Indications for Use:

CIBASOFT® PROGRESSIVE TORIC (tefilcon) soft (hydrophilic) contact lenses are indicated for daily wear for the correction of refractive ametropia (myopia, hyperopia, astigmatism and presbyopia) in aphakic or not aphakic persons with non-diseased eyes. The lenses may be worn by persons who have 0.75 to 2.75 diopters of refractive and/or corneal astigmatism that does not interfere with visual acuity.

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use: ☒ or Over-the-Counter: ☐

Laura Warburton 12/6/02

(Division Sign-Off)
Division of Ophthalmic Ear,
Nose and Throat Devises

510(k) Number K023732